

Certificate of Analysis

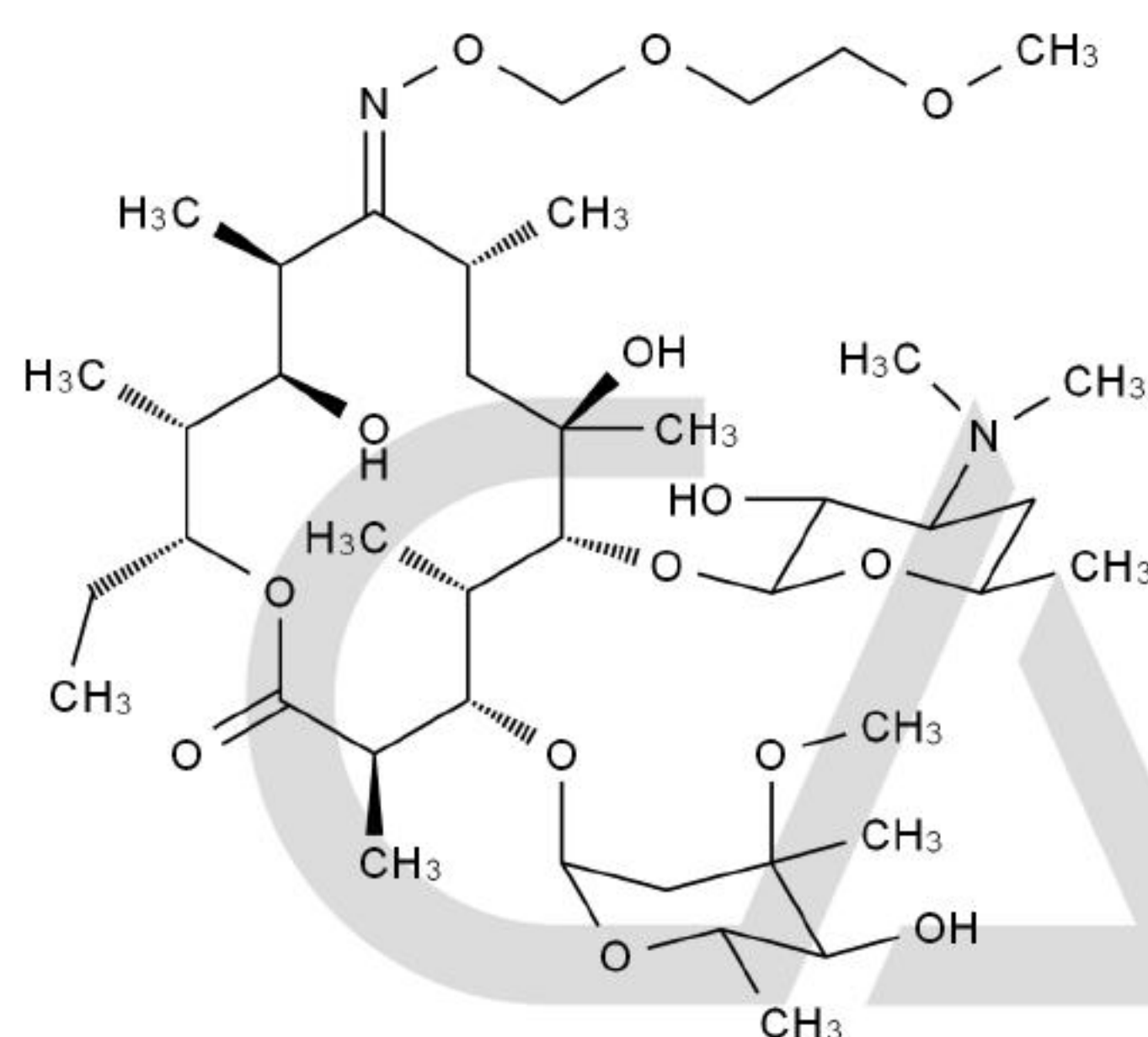
Reference Material & Standard

Product Name:	Roxithromycin EP Impurity H	Catalogue Number:	C4X-13038
Synonyms:	N/A	Lot Number:	0123-RH-0023
CAS Number:	425365-65-7	Expiry Date:	Mar 19, 2029
Molecular Formula:	C ₄₁ H ₇₆ N ₂ O ₁₄	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	821.05	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	96.903%
Water Content	Karl Fischer	1.57%
Residual Solvents	NMR	Not detected in NMR
Assay		95.4%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Jan 23, 2026

Date: Jan 23, 2026

Date: Jan 23, 2026



Add: 3rd Floor, Building B, No.179, Guangpu Rd East, Huangpu District, Guangzhou, China

Tel: +86-20-81960175

Email: supports@cato-chem.com

Web: <https://www.cato-chem.com>

